

SAN LUIS VALLEY REGIONAL MEDICAL CENTER, INC.

CORPORATE INTEGRITY AGREEMENT

This Corporate Integrity Agreement ("the Agreement") is entered into between San Luis Valley Regional Medical Center, Inc. and Lutheran Hospital Association of the San Luis Valley, d/b/a San Luis Valley Regional Medical Center (collectively, "Hospital") and the Office of Inspector General of the United States Department of Health and Human Services. This Agreement shall be effective upon the date of the last signatory hereto (the "effective date of this Agreement").

I. Preamble

The Hospital agrees to implement at its own cost, the following corporate integrity program to ensure full and accurate compliance with all Medicare and Medicaid regulations and program requirements.

II. Corporate Integrity Program

For five years from the effective date of this Agreement, the Hospital agrees to pursue the following course of action to comply with the Medicare and Medicaid regulations and program requirements applicable to the Hospital and any third parties whose services are contracted for by the Hospital.

A. Compliance Committee.

The Hospital shall create a three person compliance committee. The individuals shall be the Chief Executive Officer, the Assistant Administrator, and the Director of the Laboratory. The compliance committee will ensure that the corporate integrity requirements are implemented, be the signatory for any certifications, reports, or requests to the Office of Inspector General, and be responsible for implementing corrective action for any disclosures of billing inaccuracies or discrepancies as set forth in subparagraphs II(F) and II(G). Within thirty (30) days of the effective date of this agreement, the names of the individuals in the compliance committee, along with the specification of their job responsibilities, shall be reported to the address specified in paragraph IV.

B. Written Policies and Procedures.

The Hospital agrees to develop the following written policies and procedures governing the submission of claims to the Medicare and Medicaid programs and to distribute them to all individuals affected by those policies and procedures, including, but not limited to, laboratory and billing personnel and their supervisors.

(1) Policies and procedures to ensure that claims for laboratory testing services submitted to the Medicare and Medicaid programs are accurate, correctly identify the services ordered by the physician, and the services are medically necessary.

(2) Policies and procedures to ensure that no more than one venipuncture per day per patient is billed to the Medicare and Medicaid programs, even if multiple venipunctures are performed.

(3) Policies and procedures to ensure that telemetry services are correctly billed to Medicare and Medicaid programs.

(4) Policies and procedures to ensure that when billing for emergency room services, separate claims for EKG interpretations and/or rhythm strip interpretations are not also submitted to the Medicare or Medicaid program.

(5) Policies and procedures to ensure that when billing for a small bowel procedure, a separate claim for a UGI procedure is not also submitted to the Medicare or Medicaid program.

(6) Policies and procedures to ensure that when billing for a laser surgery procedure, an additional claim for a stab incision is not also submitted to the Medicare or Medicaid program.

C. Training.

The Hospital agrees to require regular, annual, training of billing and laboratory personnel and their supervisors, including any personnel involved in drafting, recommending or approving billing policies or procedures. Such training will be mandatory, should be conducted at repeated and regularly scheduled times by qualified individuals so that all can participate, and should cover the Hospital's Medicare and Medicaid billing compliance policies and procedures and applicable federal and state laws and regulations. Any new employees falling within the categories set forth above shall complete such training within ten days of employment. Such training should reinforce the need for strict compliance with the law and the Hospital's policies, and should inform the individuals that any failure to comply with the training requirement, the Hospital's policies, or the law may result in disciplinary action, including discharge.

D. Disclosure Program.

The Hospital shall establish a confidential disclosure program enabling employees or contractors to disclose any practices or billing procedures deemed by the employee or contractor to be inappropriate, to the compliance committee or an identified individual not in the direct chain of command of the employee or contractor. Such disclosure program shall be communicated to all Hospital employees and contractors by either posting signs throughout the Hospital or sending informational memoranda twice yearly to each employee and contractors. The Hospital shall require internal review of any such disclosure and ensure that any complaint is investigated, and, if a material violation (as defined in this Agreement) is found to follow the procedures for such violations as described herein. The compliance committee shall maintain a record of all such disclosures and a summary of final action taken. This record shall be subject to review by the OIG and a summary of all disclosures shall be included in the annual report.

E. Publication.

The Hospital shall place the following notification in the employee manual and in conspicuous places throughout the Hospital:

It is the policy of the Medical Center to conduct its operations in accordance with all applicable laws and regulations. In particular, it is essential that all billings by the Medical Center be properly submitted and documented and that Medicare and Medicaid billings comply with all regulations and procedures. Deviations from this policy may result in disciplinary action, up to and including discharge. Personnel who believe that violations of this policy may have occurred should contact the Assistant Administrator at extension _____.

F. Audits.

The Hospital agrees to perform annual audits of its claims submitted during the previous twelve months for all outpatient items and services to ensure compliance with all applicable Medicare and Medicaid federal and state laws, regulations, policies, and corporate integrity requirements contained herein, including, but not limited to the medical necessity of such claims. The audits shall be based upon a statistically valid sampling conforming to generally accepted accounting principles. The audits shall be conducted by an independent review organization, such as a

law firm or an accounting firm, with experience and expertise in billing to the Medicare and Medicaid programs. Prior to contracting with such an organization, the Hospital may, at its option, submit the name of the independent review organization and its qualifications to the address in paragraph IV, with a request that if the Office of Inspector General has any reservations concerning that organization to discuss them with the Hospital within thirty days. The first such audit will occur no later than one year from the effective date of this Agreement.

G. Reporting.

If during the course of the annual audit or at any other time, the Hospital learns of any material violation(s) of Medicare or Medicaid law or regulations, the Hospital will promptly report such material violation(s) to the address set forth in paragraph IV. For purposes of this paragraph only, a material violation is one where there is more than an isolated billing error on a single claim. The report to HHS/OIG will include: (1) the findings concerning such material violation(s); (2) the actions taken to correct such violation(s), including when the overpayments were refunded or offered to be refunded to the appropriate individual or entity; and (3) other further steps to prevent such violation(s) from recurring. A corrective action plan to remedy the systemic cause which led to the material violation(s) shall be in place within 30 days, including the proof that any overpayment has been refunded to the relevant program or offered to be refunded to the appropriate individual or entity. Documentation demonstrating a return of an overpayment should be kept by the compliance committee and the CFO. Failure to conduct an audit or failure to submit a certified report notifying HHS/OIG of any material violation(s) would be considered a material breach of this Agreement and may result in the HHS/OIG conducting its own audit, at the expense of the Hospital. Neither the reporting of information, the adoption of a corrective action plan, nor any refunding of an overpayment pursuant to this subparagraph shall be deemed an admission by the Hospital of any violation of any Federal or State law or regulation, a material breach of this agreement, or of any other wrongdoing.

H. Certifications

A member of the compliance committee shall annually certify, upon penalty of perjury, that the corporate integrity requirements contained in this Agreement have been met. In addition, a copy of the independent audit report required in subparagraph II(F) and any reports required by subparagraph II(G) shall be submitted. The certification

and report shall be submitted to the address specified in paragraph IV, no later than 14 months after the effective date of this Agreement with annual submissions due each year after that date for four more years.

I. Duty to Inquire.

The Hospital will not employ, with or without pay, or enter into a contract or business relationship with any individual or business entity whom the Hospital knows or should have known has been convicted of a criminal offense which would trigger an exclusion pursuant to 42 U.S.C. § 1320a-7(a) or 42 U.S.C. § 1320a-7(b) unless that person or entity has been reinstated, or is listed by a federal agency as currently suspended, debarred, excluded or otherwise ineligible for federal program participation. In order to carry out this requirement, the Hospital agrees to make reasonable inquiry into the status of any potential employee, agent, or contractor, including review of HHS/OIG Cumulative Sanctions Report (accessible on the Internet at the IG Webset: [HTTP://WWW.DHHS.GOV/PROGORG/OIG](http://WWW.DHHS.GOV/PROGORG/OIG)) and the General Services Administrative (GSA) List of Parties Excluded from Federal Procurement and Non-Procurement Programs (accessible on the Internet at [HTTP://WWW.ARNET.GOV/EPLS](http://WWW.ARNET.GOV/EPLS)).

III. Inspections.

In addition to any other right that HHS/OIG may have by statute, regulation, contract or pursuant to this paragraph, HHS/OIG or its duly authorized representative(s) (this would not include a competitor of the hospital), may at any time within five years after the effective date of this Agreement, examine the Hospital's books, records, and other documents and supporting materials for the purpose of verifying and evaluating (i) the Hospital's compliance with the terms of this Agreement; (ii) the Hospital's business conduct in its dealing with the United States government, or any agencies or agents thereof; and (iii) the Hospital's compliance with the requirements of the Medicare and Medicaid programs and other Federal health care programs (as defined by 42 U.S.C. §1320a-7b(f)). The documentation described above shall be made available by the Hospital at all reasonable times during such five year period, for inspection, audit or reproduction. Furthermore, for purposes of this provision, HHS or its authorized representative(s) may interview any Hospital employee or contractor who consents to be interviewed at the place of business during normal business hours, with appropriate notice, or at such other place and time as may be mutually agreed upon between the employee and HHS. If an interview of a current employee or contractor is initiated by HHS/OIG or its duly authorized representative(s) for purposes of determining compliance with the corporate integrity requirements contained

herein, the Hospital will be notified first. Employees or contractors may elect to be interviewed with or without a representative of the Hospital present.

IV. Address

All documents, reports, certifications, and requests for approval, shall be sent to the following address: ATTN: Office of Counsel for the Inspector General, Civil Recoveries Branch - Compliance Unit, Office of Inspector General, United States Department of Health and Human Services, Cohen Building, Room 5527, 330 Independence Avenue, S.W., Washington, D.C., 20201, (202)619-2708. Any modifications to the requirements set forth in this paragraph must be set forth in writing and agreed to by the Office of Inspector General.

V. Applicability

The corporate integrity requirements set forth in this paragraph shall apply to any successor corporation, including a new company formed by an asset purchase, regardless of whether a new provider number is sought.

VI. Document and Record Retention

For a period of six (6) years following the effective date of this Agreement, the Hospital shall maintain for inspection, all documents and records relating to the implementation and maintenance of this Agreement.

VII. Breach & Default Provisions

The Hospital's compliance with the terms and conditions of this Agreement shall constitute an element of the Hospital's present responsibility with regard to participation in Federal health programs. The Hospital's material failure to meet any of its obligations pursuant to the terms and conditions of this Agreement constitutes a separate cause for exclusion.

In the event that HHS/OIG believes that the Hospital has materially breached one or more of its obligations under the Agreement, HHS/OIG shall notify the Hospital of the alleged breach by certified mail, specifying the nature and extent of the alleged breach. The Hospital will have thirty (30) days from receipt of the notice to: (a) cure said breach; or (b) otherwise satisfy the government that it is (1) in full compliance with this Agreement, or (2) that the breach cannot be reasonably cured within 30 days, but that the Hospital has taken action to cure the breach and is pursuing such action with diligence.

If, at the end of the thirty day period described above, HHS/OIG determines that the Hospital continues to be in material

breach of one or more of its obligations under this Agreement, HHS/OIG may, in writing and by certified mail, declare the Hospital to be in default and initiate proceedings to suspend or exclude the Hospital from participation in the Title XVIII (Medicare) program, the Title XIX (Medicaid) program and other Federal health care programs as defined in 42 U.S.C. Section 1320a-7b(f) until such time as the breach is cured. The document by which HHS/OIG may declare the Hospital to be in default and notify the Hospital of HHS/OIG's intention to exclude shall be hereafter referred to as the "Notice of Intention to Exclude Letter." In the event the Hospital fully cures the material breach or otherwise satisfies HHS/OIG, there will be a prompt reinstatement, retroactive to the date of cure.


Upon receipt by the Hospital of HHS/OIG's Notice of Intention to Exclude Letter, the Hospital shall be entitled to the due process afforded a provider under 42 U.S.C. Section 1320a-7(f). Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a breach of this Agreement shall be: (1) whether the Hospital was in material breach of one or more of its obligations under this Agreement, at the time of and as specified in the Notice of Intention to Exclude Letter; (2) whether such breach was continuing on the date on which HHS/OIG notified the Hospital of its proposal to exclude; and (3) whether the Hospital failed to cure the material breach within 30 days after receiving notice thereof from HHS/OIG, or, if the breach could not be reasonably cured within 30 days, failed, within that time, to take action to cure the breach and to pursue such action with diligence. After an Administrative Law Judge's decision concerning such exclusion, any reinstatement must be in accordance with 42 C.F.R. § 1001.3001.

This Agreement may be signed in counterparts and each counterpart will be considered an original agreement.

IN WITNESS WHEREOF, the parties hereto affix their signatures.

FOR THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

12/7/97
Date



Lewis Morris
Assistant Inspector General for Legal
Affairs
Office of Counsel to the Inspector
General
Office of Inspector General

FOR SAN LUIS VALLEY REGIONAL MEDICAL CENTER, INC.

12-16-97
Date

Paul S. Herman
Chief Executive Officer
106 Blanca Avenue
Alamosa, Colorado 81101
(719) 589-2511

FOR LUTHERAN HOSPITAL ASSOCIATION OF THE SAN LUIS VALLEY

12-16-97
Date

Paul S. Herman
Chief Executive Officer
106 Blanca Avenue
Alamosa, Colorado 81101
(719) 589-2511

Dec. 19, 1997
Date

Gale T. Miller
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Provider Number